

REMARKS/ARGUMENTS

Claims 1-10 are pending. Claims 1-10 have been finally rejected. Applicants request reconsideration of the outstanding rejections against the claims in view of the following remarks. No new matter is presented.

Rejections under 35 U.S.C. §§102(b)/103(a)

The Examiner asserts claims 1-10 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S.P.N. 6,365,768 to Palladino (hereinafter Paladino).

Applicants' claim 1 defines fully the extract procedure as relating to a water extract of *Acanthopanax koreanum* which does not contain acanthoic acid, thereby distinguishing the Applicants' claimed invention from Palladino. According to the extract procedure described in claim 1, the extract of *Acanthopanax koreanum* is obtained by using only water, not by using organic solvent including methanol or ethanol which in turn produces an extract containing acanthoic acid as taught by Palladino. Therefore, the water extract of Applicants' claim 1 cannot include acanthoic acid in contrast to the extract taught by Palladino.

As Applicants set forth in the response dated January 19, 2007 to the Office Action dated July 19, 2006, the extract of *Acanthopanax*

koreanum recited in Applicants' claim 1 does not contain acanthoic acid. The extract of *Acanthopanax koreanum* of Applicants' claim 1 relates to a water extract that does not contain acanthoic acid. This finding is supported in the working examples of Applicants' disclosure and the experiments set forth in the Declaration of Jung Joon Lee dated January 8, 2007. That is, in order for the extract of the root or stem of *Acanthopanax koreanum* to contain acanthoic acid, one of ordinary skill in the art must extract *Acanthopanax koreanum* with an organic solvent, such as methanol or ethanol, as taught by Palladino. Although independent claim 1 contains open claim language, that is, the term "comprising", a term cannot necessarily be read into the claim which significantly alters the properties of the composition. Applicants' claim 1 clearly defines the extract procedure of the root or stem of *Acanthopanax koreanum* which utilizes only water, thus basic scientific principles dictate the extract of *Acanthopanax koreanum* of Applicants' claim 1 cannot contain acanthoic acid.

When reviewing Applicants dependent claims, claim 2 relates to the extract of *Acanthopanax koreanum* containing an insoluble ethanol part, that is, the precipitate, obtained when the water extract of claim 1 is treated with ethanol. The precipitate or insoluble ethanol part cannot contain acanthoic acid insofar as the water extract does not contain acanthoic acid. Dependent claims 3 to 6 are

also directed to the water extract and, thus, do not contain acanthoic acid. And, claims 7 to 10 relate to a pharmaceutical composition containing the extract of *Acanthopanax koreanum* of any one of claims 1 to 4 which cannot contain acanthoic acid. As a result, claims 7 to 10 cannot contain acanthoic acid.

The examiner asserts that "the reference product reasonably appears to be the same product as claimed because the reference product is extracted from the same source as claimed and has the same TNF- α (i.e. Tumor Necrosis Factor- α , an inhibitory activity and viral infection (i.e. hepatitis)" (See Final Office action dated March 2, 2007). However, it can be easily anticipated that the extract of *Acanthopanax koreanum* of Applicants' claim 1 and that of the cited references are totally different products based on a chemical theory that a solubility of a specific material is dependent upon the solvent. That is, even if an extract is obtained from the same stem or root of the *Acanthopanax koreanum*, it is a general rule that the extracted composition varies depending upon the solvent used in the extract procedure. In particular, since water and an organic solvent, such as methanol or ethanol, are two types of extract solvents having completely different chemical properties; each solvent respectively exhibits a totally different solubility towards a specific compound, thus the extracted compositions are totally different from each other. Specifically, since the Applicants'

claimed extract is accomplished using only water, the composition of the water extract should be a hydrophilic compound. In contrast, the extract of *Acanthopanax koreanum* containing acanthoic acid disclosed in Palladino et al. is accomplished using an organic solvent containing methanol, ethanol and the like. Therefore, it can be easily anticipated that the extract of *Acanthopanax koreanum* disclosed in Palladino primarily contains a hydrophobic compound such as acanthoic acid.

The Examiner also indicated in her remarks that since both the extract recited in Applicants' claim 1 and Palladino contain TNF- α (i.e. Tumor Necrosis Factor- α , an inhibitory activity and viral infection, i.e., hepatitis), both extracts are the same product. In this connection, as fully explained in Applicants' Responses under 37 C.F.R. §1.111(a) dated May 5, 2006 and January 15, 2007, Applicants' claim 1 does not contain acanthoic acid which Palladino indicates is an effector of TNF- α production. As known to one of ordinary skill in the art there are innumerable causing material showing the same pharmaceutical effects. Moreover, the effector of TNF- α production indicated by Palladino is only acanthoic acid but is not the extract of *Acanthopanax koreanum*. In addition, Palladino provides an experiment on the inhibition of the TNF- α production using only acanthoic acid and just confirms the effects thereof.

In the alternative, even if the extract recited in Applicants'

claim 1 and Palladino teach the same effects of the inhibition of the TNF- α production, it is difficult to conclude that the extract of *Acanthopanax koreanum* of Applicants' claim 1 has the same composition as Palladino as the choice of solvent necessarily yields a different product. What brings the effects of the inhibition of the TNF- α production in Palladino is acanthoic acid which is a specific compound extracted from *Acanthopanax koreanum* using an organic solvent taught by Palladino. In contrast, Applicants' claimed extract is a composition extracted from the stem or root of *Acanthopanax koreanum* using water. This particular difference was established in the working examples of Applicants' specification and the experiments set forth in the Declaration of Jung Joon Lee dated January 8, 2007, which indicated the water extract did not contain acanthoic acid.

In light of the foregoing, Applicants respectfully request the Examiner withdraw the rejections under 35 U.S.C. §§102(b)/103(a) and find that claims 1-10 are allowable.

The Examiner rejected claims 1-10 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S.P.N. 5,900,434 to Pyun et al.

Applicants' claim 1 defines fully the extract procedure as relating to a water extract of *Acanthopanax koreanum* which does not contain acanthoic acid, thereby distinguishing the Applicants' claimed invention from Pyun. According to the extract procedure described in claim 1, the extract of *Acanthopanax koreanum* is obtained by using only water, not by using organic solvent including methanol or ethanol which in turn produces an extract containing acanthoic acid as taught by Pyun. Therefore, the water extract of Applicants' claim 1 cannot include acanthoic acid in contrast to the extract taught by Pyun.

As Applicants set forth in the response dated January 19, 2007 to the Office Action dated July 19, 2006, the extract of *Acanthopanax koreanum* recited in Applicants' claim 1 does not contain acanthoic acid. The extract of *Acanthopanax koreanum* of Applicants' claim 1 relates to a water extract that does not contain acanthoic acid. This finding is supported in the working examples of Applicants' disclosure and the experiments set forth in the Declaration of Jung Joon Lee dated January 8, 2007. That is, in order for the extract of the root or stem of *Acanthopanax koreanum* to contain acanthoic acid, one of ordinary skill in the art must extract *Acanthopanax koreanum*

with an organic solvent, such as methanol or ethanol, as taught by Pyun. Although independent claim 1 contains open claim language, that is, the term "comprising", a term cannot necessarily be read into the claim which significantly alters the properties of the composition. Applicants' claim 1 clearly defines the extract procedure of the root or stem of *Acanthopanax koreanum* which utilizes only water, thus basic scientific principles dictate the extract of *Acanthopanax koreanum* of Applicants' claim 1 cannot contain acanthoic acid.

When reviewing Applicants dependent claims, claim 2 relates to the extract of *Acanthopanax koreanum* containing an insoluble ethanol part, that is, the precipitate, obtained when the water extract of claim 1 is treated with ethanol. The precipitate or insoluble ethanol part cannot contain acanthoic acid insofar as the water extract does not contain acanthoic acid. Dependent claims 3 to 6 are also directed to the water extract and, thus, do not contain acanthoic acid. And, claims 7 to 10 relate to a pharmaceutical composition containing the extract of *Acanthopanax koreanum* of any one of claims 1 to 4 which cannot contain acanthoic acid. As a result, claims 7 to 10 cannot contain acanthoic acid.

The examiner asserts that "the reference product reasonably appears to be the same product as claimed because the reference product is extracted from the same source as claimed and has the same

TNF- α (i.e. Tumor Necrosis Factor- α , an inhibitory activity and viral infection (i.e. hepatitis)" (See Final Office action dated March 2, 2007). However, it can be easily anticipated that the extract of *Acanthopanax koreanum* of Applicants' claim 1 and that of the cited references are totally different products based on a chemical theory that a solubility of a specific material is dependent upon the solvent. That is, even if an extract is obtained from the same stem or root of the *Acanthopanax koreanum*, it is a general rule that the extracted composition varies depending on the solvent used in the extract procedure. In particular, since water and an organic solvent, such as methanol or ethanol, are two types of extract solvents having completely different chemical properties; each solvent respectively exhibits a totally different solubility towards a specific compound, thus the extracted compositions are totally different from each other. Specifically, since the Applicants' claimed extract is accomplished using only water, the composition of the water extract should be a hydrophilic compound. In contrast, the extract of *Acanthopanax koreanum* containing acanthoic acid disclosed in Pyun et al. is produced using an organic solvent containing methanol, ethanol and the like. Therefore, it can be easily anticipated that the extract of *Acanthopanax koreanum* disclosed in Pyun primarily contains a hydrophobic compound such as acanthoic acid.

The Examiner also indicated in her remarks that since both the extract recited in Applicants' claim 1 and Pyun contain TNF- α (i.e. Tumor Necrosis Factor, an inhibitory activity and viral infection, i.e., hepatitis), both extracts are the same product. In this connection, as fully explained in Applicants' Responses under 37 C.F.R. §1.111(a) dated May 5, 2006 and January 15, 2007, Applicants' claim 1 does not contain acanthoic acid which Pyun indicates is an effector of TNF- α production. Moreover, the effector of TNF- α production indicated by Pyun is only acanthoic acid and not the extract of *Acanthopanax koreanum*. In addition, Pyun provides an experiment on the inhibition of the TNF- α production using only acanthoic acid and just confirms the effects thereof.

In the alternative, even if the extract recited in Applicants' claim 1 and Pyun teach the same effects of the inhibition of the TNF- α production, it is difficult to conclude that the extract of *Acanthopanax koreanum* of Applicants' claim 1 has the same composition as Pyun as the choice of solvent necessarily yields a different product. What brings the effects of the inhibition of the TNF- α production in Pyun is acanthoic acid which is a specific compound extracted from *Acanthopanax koreanum* using an organic solvent as taught by Pyun. In contrast, Applicants' claimed extract is a composition extracted from the stem or root of *Acanthopanax koreanum* using water. This particular difference was established in the

working examples of Applicants' specification and the experiments set forth in the Declaration of Jung Joon Lee dated January 8, 2007, which indicated the water extract did not contain acanthoic acid.

In light of the foregoing, Applicants respectfully request the Examiner withdraw the rejections under 35 U.S.C.

§§102(b)/103(a) and find that claims 1-10 are allowable.

CONCLUSION

An earnest and thorough attempt has been made by the undersigned to resolve the outstanding issues in this case and place same in condition for allowance. If the Examiner has any questions or feels that a telephone or personal interview would be helpful in resolving any outstanding issues which remain in this application after consideration of this amendment, the Examiner is courteously invited to telephone the undersigned and the same would be gratefully appreciated.

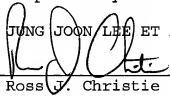
It is submitted that the claims herein patentably define over the art relied on by the Examiner and early allowance of same is courteously solicited.

If any additional fees are required in connection with this case, it is respectfully requested that they be charged to Deposit Account No. 02-0184.

Respectfully submitted,

JUNG JOON LEE ET AL.

By



Ross J. Christie
Attorney for Applicants
Reg. No. 47,492
Tel: (203) 777-6628 x.116
Fax: (203) 865-0297